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10/602,129	06/24/2003	Scot R. Shepard	2001.689USD1	1596
67706 7590 08/07/2009 ORGANON USA, INC. c/o Schering-Plough Corporation 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033				
EXAMINER MCMILLIAN, KARA RENTA				
ART UNIT		PAPER NUMBER		
1617				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/602,129

Applicant(s)

SHEPARD, SCOT R.

Examiner

KARA R. MCMILLIAN

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 12, 16-20 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 12, 16-20 and 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 3-6-09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 6, 2009 has been entered.

Response to Arguments/Amendments

The applicant's amendments received on March 6, 2009 amending claim 10, canceling claims 11, 13, 14 and 21-24 and adding new claims 30-34 have been entered. Claims 1-9 and 15 were previously canceled. Currently claims 10, 12, 16-20 and 25-34 are pending.

Applicant's arguments filed March 6, 2009 with respect to the rejection under 35 USC § 102 (e) have been fully considered but they are not persuasive. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Applicants state that claims 18-20 are directed to a method of inactivating a viral or microbial agent in a biological source material, comprising a step of contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide. Applicants further state that the term "consisting essentially of" refers to a solution which consists of the selected active ingredient and only minor amounts of non-essential ingredients. Applicants have provided no arguments as to why Birnie et al. do not anticipate said claims. Applicant should submit an argument pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

Birnie et al. teach compositions containing an N-alkyl-N,N-dimethylamine oxide including dimethyldecylaminooxide or dimethyldidecylamineoxide inhibit the growth of bacteria. Birnie et al. teach contacting bacterial cells with a solution containing an amine oxide wherein the growth of bacteria cells are inhibited thus claims 18-20 are anticipated. As claims 21-24 have been canceled said rejection is now moot with respect to those claims.

Applicant's arguments filed March 6, 2009 with respect to the rejections under 35 USC § 103 over Fonsny et al. have been fully considered but they are not persuasive.

Applicants state what Fonsny et al. teach and state the claimed invention and assert that the term consisting essentially of refers to a solution which consists of the selected active ingredient amine or amine oxide, either with or without a polyol and minor amounts of non-essential ingredients. The examiner respectfully points out that

for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Applicants further assert that the present invention is directed to the use of biological materials as sources of medicinal and industrial intermediates and products and that Fonsny et al. fail to teach or suggest the use of amine oxides to inactivate a viral or microbial agent while not denaturing or destroying the biomolecule of interest. This argument is found not persuasive because Applicants are arguing limitations that are not presented in the current claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., biological materials as sources of medicinal and industrial intermediates and products and the use of amine oxides to inactivate a viral or microbial agent while not denaturing or destroying the biomolecule of interest) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The present claims read a method of inactivating a viral or microbial agent in a biological source material. Fonsny et al. broadly teach the use of disinfectant compositions for the purpose of sanitizing and disinfecting surfaces, thus biological materials are inclusive. Fosny et al. teach that these compositions have bactericidal effects thus microbial agents are inactivated.

Applicant's arguments filed March 6, 2009 with respect to the rejections under 35 USC § 103 over Michaels et al. have been fully considered but they are not persuasive.

Applicants argue that the instant claims require the solution to consist essentially of alkyldimethylamine oxides, with or without a polyol. The examiner respectfully points out that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Applicants further argue that the claimed invention provides a method which does not denature or destroy a biomolecule of interest and that Michaels fails to teach or suggest the use of a solution of an amine oxide to inactivate a viral or microbial agent

while not denaturing or destroying the biomolecule of interest. This argument is found not persuasive since Applicants are arguing limitations that are not present in the claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. the use of a solution containing amine oxides to inactivate a viral or microbial agent while not denaturing or destroying the biomolecule of interest) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For reasons of record and for the reasons presented above the previous rejections of the claims are hereby maintained. However, as a result of Applicant's amendments, modified rejections incorporating all pending claims are detailed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Birnie et al. (Antimicrobial Evaluation of N-Alkyl Betaines and N-Alkyl-N,N-dimethylamine

Oxides with Variations in Chain Length, Sept. 2000, Antimicrobial Agents and Chemotherapy, Vol. 44, No. 9, pp. 2514-2517).

Claims 18-20 of the instant application claim a method of inactivating a viral or microbial agent in a biological source material, comprising contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide.

The examiner respectfully points out that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of" is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps

included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

Birnie et al. teach, in the abstract of page 2514, that alkyl betaines and alkyl dimethylamine oxides have been shown to have pronounced antimicrobial activity when used individually or in combination. In Table 3 on page 2515, Birnie et al. show the activity of N-alkyl-N,N-dimethylamine oxides against the bacteria *S. aureus* and *E. coli* as a function of alkyl chain length. Table 3 clearly indicates that N-alkyl-N,N-dimethylamine oxides have antimicrobial activity, including the amine oxides currently claimed. Specifically claims 18-20 of the instant application claim dimethyldecylaminooxide which is equivalent to C₁₀ amine oxide and dimethyldidecylamineoxide which is equivalent to C₁₂ amine oxide (see Table 3 page 2515).

Birnie et al. also teach effective concentrations of N-alkyl-N, N-dimethylamine oxide within the range claimed in the instant application (see Table 3 on page 2515). Thus claims 18-20 are anticipated by Birnie et al.

Claim Rejections - 35 USC § 103

Claims 10, 12, 16-20 and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonsny et al. U.S. Patent No. 5,911,915 in view of Rasmussen et al. Publication No. US 2002/0022649 A1.

Claims 10, 12, 16 and 17 of the instant application claim a method of inactivating a viral or microbial agent in a biological source material, comprising contacting the

biological source material with a solution comprising an effective amount of an amine, wherein the amine is selected from the group consisting of: dimethyldodecylamine, dimethyltridecylamine, dimethylundecylamine, dimethyldidecylamine, dimethyltetradecylamine, and dimethylhexadecylamine. Claims 18-20 of the instant application claim a method of inactivating a viral or microbial agent in a biological source material, comprising contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldodecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide. Claims 25-29 of the instant application also claim the method of claims 18-20 wherein the solution consists essentially of a polyol and an amine oxide. Claims 30-34 of the instant application claims the method of claims 10, 12, 16 and 17 wherein the solution consists essentially of a polyol and an amine.

The examiner respectfully points out that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12

USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.").

Fonsny et al. disclose a stable, clear, multipurpose, hard surface cleaning composition especially effective in disinfecting the surface being cleaned (see column 2 lines 19-21). The composition disclosed by Fonsny et al. comprises among other ingredients, 0.1% to 20% of a nonionic surfactant and/or an ethoxylated glycerol type compound, 0.1% to 20% of at least one disinfecting agent such as a cationic surfactant, and 0.1% to 20% of an amphoteric surfactant (see column 2 lines 47-58). Fonsny et al. further disclose that the compositions contain preferably 0.25% to 8% of a disinfectant agent selected from C₈-C₁₆ alkyl amines, and that amine oxides can be optionally used at a concentration of 0 to 10%, more preferably 0.1% to 8% (see column 8 lines 45-67). Fonsny et al. further disclose in column 9 lines 1-13 the formula of suitable amine oxides which can be any one of the amine oxides claimed in claims 18 and 25 of the instant application.

Fonsny et al. do not specifically exemplify the amines and amine oxides as claimed in the instant invention. However, Fonsny et al. broadly disclose C₈-C₁₆ alkyl

amines and C₁₀-C₁₈ alkyl amine oxides useful as disinfectants which renders the amines and amine oxides claimed in the instant application obvious (see column 8 lines 45-67 and column 9 lines 14-59).

Fonsny et al. do not specifically teach the exact ranges of each of the components claimed in the instant application. However Fonsny et al. disclose ranges of each of the components claimed in the instant application that overlap with the ranges claimed in the instant application.

Fonsny et al. do not specifically disclose the inclusion of glycerol in the disinfectant composition.

Fonsny et al. disclose the use of 0.1% to 20% of a nonionic surfactant and/or an ethoxylated glycerol type compound (see column 2 lines 49-50).

Rasmussen et al. teach in paragraph [0075] that glycerol is a nonionic surfactant.

Accordingly, one of ordinary skill in the art at the time of the instant invention would have found it obvious to combine the teachings of Fonsny et al., which teach the use of 0.1% to 20% of a nonionic surfactant in a disinfectant composition with the teachings of Rasmussen et al. which teach that glycerol is a nonionic surfactant. Thus, since the composition of Fonsny et al. calls for the inclusion of a nonionic surfactant, and glycerol is a known nonionic surfactant (as disclosed by Rasmussen et al.) one of ordinary skill in the art would be motivated to include glycerol in the composition disclosed by Fonsny with a reasonable expectation of similar success in providing a disinfectant composition.

Regarding claim 16, it would be obvious to an ordinary skilled artisan that any composition that contains surfactants such as those disclosed in the compositions of Fonsny et al. would lyse bacteria. Thus claim 16 is also rendered obvious by Fonsny et al.

In conclusion claims 10, 12, 16-20 and 25-34 of the instant application are rendered obvious by Fonsny et al. in view of Rasmussen et al. since Fonsny et al. disclose disinfectant compositions comprising amines or amine oxides and Rasmussen et al. obviate the inclusion of glycerol in the composition.

Claims 18-20 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaels, U.S. Patent No. 5,389,676.

Claims 18-20 of the instant application claim a method of inactivating a viral or microbial agent in a biological source material, comprising contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide. Claims 25-29 of the instant application also claim the method of claims 18-20 wherein the solution consists essentially of a polyol and an amine oxide.

The examiner respectfully points out that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are,

"consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In *re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of" is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of language.").

Michaels teaches, in column 2 lines 20-45 compositions comprising surfactants including amine oxides with increased viscosity for use in the formulation of disinfectants. The compositions can be used in the treatment of mammalian tissue or cells with less irritation than the usual surfactants used for cleaning and disinfecting. Michaels further teaches that the surfactants useful as disinfectants and can be used in the treatment of damaged skin. Michaels discloses in column 3 line 63 through column 4 line 3 examples of amine oxides including decyl-N,N-dimethylamine oxide (equivalent to the dimethyldecylamineoxide).

Michaels teaches in column 5 lines 38-57 that preferred compositions contain 0.1-10% of the active ingredient one of which is the amine oxide. Michaels further teaches, in col. 10 lines 20-60, zone of inhibition tests against bacteria *S. sanguis* M5 performed using a composition comprising 0.5% of C31G (a 1:1 betaine to amine oxide composition), and 5% glycerin (equivalent to glycerol).

Michaels does not specifically exemplify a composition comprising one of the amine oxides claimed in claims 18 and 25 of the instant application.

However, Michaels does disclose that decyl-N,N-dimethylamine oxide (equivalent to the dimethyldecylamineoxide) is an example of an amine oxide useful in the anti-infective or disinfectant composition (see column 3 lines 63-64). Michaels discloses numerous amine oxides useful in the anti-infective or disinfectant composition. As such, an ordinary skilled artisan would be motivated to use any of the amine oxides listed in Michaels (see column 3 line 63- column 4 lines 3) with a reasonable expectation of similar success. As such claims 18-20 and 25-29 are rendered obvious in view of the teachings of Michaels.

Conclusions

Claims 10, 12, 16-20 and 25-34 are rejected. Claims 1-9, 11, 13-15 and 21-24 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is

(571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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